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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,408	10/01/2003	Gilbert Rene Gonzales	PEDI-13	8069
26875 7590 03/23/2007 WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT	PAPER NUMBER
			1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/676,408

Applicant(s)

GONZALES ET AL.

Examiner

Jagadishwar R. Samala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-36 and 47-50 is/are pending in the application.
4a) Of the above claim(s) 1-26, 37-46 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-36 and 47-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 01/12/04; 07/11/05 & 01/08/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election Acknowledged

1. Applicant's election without traverse of group II in the reply filed on October 1, 2003 is acknowledged. Election is made Final. Claims 27-36 and 47-50 are presented for examination. Non elected claims 1-26, 37-46 and 51 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 27, 32-36 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schobel (US 4,687,662).

With respect to claims 27, 32-36 and 47-50, the '662 patent discloses a method for oral administration of effervescent composition in the form of tablets or powders comprising a therapeutic agent, a granulating agent, a microparticulate effervescent component and an effervescent system which dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent (see column 3, lines 10-12 and abstract). And also the granulating agent may be selected from group

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consisting of water, alcohol, sucrose, hydroxypropyl cellulose and causes slow disintegration of therapeutic agent and release gas (see column 4, lines 17-28). The effervescent system may comprise one or more components, preferably a carbonate containing material and an acid and mixtures thereof. The acids which may be employed are compounds capable of reacting with carbonate containing materials to cause the release of carbon dioxide when contacted with sufficient water (see column 5, lines 14-18 and lines 45+). The oral administration of effervescent composition advanced by Schobel provides granulating agents such as water, alcohol, sucrose, hydroxypropyl cellulose and natural and artificial sweeteners. Since the essential elements of the cited reference are identical to the instant claims (i.e. gas dispersing component including a solid matrix), would inherently have the same physiochemical properties as set forth in the instant application. As such the method for oral administration advanced by Schobel anticipates the instant claims set.

4. Claims 27-36 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Wehling et al. (US 5,223,264).

Wehling discloses a oral effervescent dosage forms for the administering a mixture of at least one effervescent disintegrating agent, and a pediatrically effective amount of at least one intended ingredient in the form of tablet (see column 2, lines 31-45). The effervescent agent includes compounds, which evolve gas by means of chemical reactions, which takes place upon exposure of the effervescent agent to produce carbon dioxide, oxygen or other gases (which are pediatrically safe) upon

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contact with water including saliva or simple gastric fluids. The said effervescent agent is effective both to aid in the rapid disintegration of tablet and provide a positive organoleptic sensation to children (column 5, lines 9-38). The dosage form further includes one or more additional adjuvants such as cellulose materials (methyl cellulose and sodium carboxy methyl cellulose), polysaccharides, sugars, invert sugars and the like (see column 6, lines 50-54). The tablets include surface markings, cuttings, grooves, letters and or numerals for the purpose of easy consumption by child (see column 3, lines 54-60). And also discloses a process of administering intended ingredient medicament to a child, so that tablet disintegrate in the child's mouth to provide a controlled drug delivery system and increased absorption of drug (see column 3, lines 29-29).

The oral administration of effervescent composition advanced by Wehling provides additional adjuvants such as cellulose materials (methyl cellulose and sodium carboxy methyl cellulose), polysaccharides, sugars, invert sugars and the like. Since the essential elements of the cited reference are identical to the instant claims (i.e. gas dispersing component including a solid matrix), would inherently have the same physiochemical properties as set forth in the instant application. As such the method for oral administration advanced by Wehling anticipates the instant claims set.

Conclusion

1. No claims are allowed at this time.

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2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER